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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,414	03/10/2006	Frank Theobald	R04209US (#90568)	3449

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EXAMINER	
MI, QIUWEN	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
06/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,414	THEOBALD ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *13-24 and 34-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 2/14/08 is acknowledged.

Claims Pending

Claims 1-44 are pending. Claims 13-24, and 34-44 are withdrawn as they are directed toward non-elected invention groups. Claims 1-12, and 25-33 are examined on the merits.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7-11, 25-27, and 31-33 main rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al (US 6,090,403).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/13/2007. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Applicant amends claim 1 as:

at least one essential oil "inhalable as a decongestant";

at least one hydrophile polymer "for incorporating and for delivering said at least one essential oil for the treatment of colds";

at least one substance having an adsorbent effect "and to prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase"

at least one pressure-sensitive adhesive polymer "for adhering said patch to the skin",

The intended use of the composition in quotation mark was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims. More specifically, it is deemed that the essential oils menthol and camphor are inhalable as a decongestant; the hydrophyile polymer gum karaya could deliver the essential oils menthol and camphor for the treatment of colds and prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase; and the pressure-sensitive adhesive polymer could adhere patch to the skin.

Claims 1-11, 25-29, and 31-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), and Kelley (US 2003/0167556).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/13/2007. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Applicant amends claim 1 as:

at least one essential oil "inhalable as a decongestant";

at least one hydrophile polymer "for incorporating and for delivering said at least one essential oil for the treatment of colds";

at least one substance having an adsorbent effect "and to prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase"

at least one pressure-sensitive adhesive polymer "for adhering said patch to the skin",

The intended use of the composition in quotation mark was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims. More specifically, it is deemed that the essential oils menthol and camphor are inhalable as a decongestant; the hydrophyile polymer gum karaya could deliver the essential oils menthol and camphor for the treatment of colds and prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least

one essential oil phase; and the pressure-sensitive adhesive polymer could adhere patch to the skin.

Claims 1-11, and 25-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), Kelley (US 2003/0167556), and Kamiya et al (US 5,780,047).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/13/2007. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Applicant amends claim 1 as:

at least one essential oil "inhalable as a decongestant";

at least one hydrophile polymer "for incorporating and for delivering said at least one essential oil for the treatment of colds";

at least one substance having an adsorbent effect "and to prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase"

at least one pressure-sensitive adhesive polymer "for adhering said patch to the skin",

The intended use of the composition in quotation mark was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims. More specifically, it is deemed that the essential oils menthol and camphor are inhalable as a decongestant; the hydrophyile polymer gum karaya could deliver the essential oils menthol and camphor for the treatment of colds and prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase; and the pressure-sensitive adhesive polymer could adhere patch to the skin.

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Claims 1-12, and 25-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Block et al (US 6,090,403), Kamiya et al (US 5,780,047), Kelley (US 2003/0167556), and Merkle et al (US 5,527,536).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 9/13/2007. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Applicant amends claim 1 as:

at least one essential oil "inhalable as a decongestant";

at least one hydrophile polymer "for incorporating and for delivering said at least one essential oil for the treatment of colds";

at least one substance having an adsorbent effect "and to prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase"

at least one pressure-sensitive adhesive polymer "for adhering said patch to the skin",

The intended use of the composition in quotation mark was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims. More specifically, it is deemed that the essential oils menthol and camphor are inhalable as a decongestant; the hydrophyile polymer gum karaya could deliver the essential oils menthol and camphor for the treatment of colds and prevent the occurrence of phase separation between the at least one hydrophile matrix polymer and the at least one essential oil phase; and the pressure-sensitive adhesive polymer could adhere patch to the skin.

Answer to Applicant's Argument

Applicant summarizes the previous Office Action (pages 12-13) and states Applicant argues that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Applicant states what Block

et al teach (page 14, last paragraph; page 15, 1st and 2nd paragraphs) and argues the medicinal patch of the present invention and the skin patch set forth in Block, et al. are fundamentally different in their respective approaches of how to support drug-loading and release of the decongestant" (page 14, 2nd paragraph from the bottom); and "Block, et al. does not have a backing layer (as in the case of the present invention and as set forth in the present claims), as a backing layer and foraminous carrier are clearly distinct elements with respect to their structure and function within the different patches. The backing layer of the medicinal skin patch of the present invention is clearly not a carrier for the decongestive inhalant, but rather prevents soiling of the user's clothing. The medicinal skin patch of the present invention contains the inhalable essential oil in a polymer matrix, as is evidence from its manufacturing process, is not spread over a large surface of a foraminous carrier. In fact, a patch of the present invention does not have a foraminous carrier but rather the matrix is a compact, non-foraminous structural element of the medical skin patch of the present invention" (page 15, last paragraph).

This is not found persuasive. Block et al clearly state that "The patch includes an underlying layer (thus a back layer) of non-irritating medical grade pressure-sensitive adhesive, and a foraminous upper carrier layer to which the decongestant-containing ointment is applied" (col 5, lines 4-10). Thus, Block et al teach a back layer. In addition, since the current claims use open language "comprising", the claim language does not preclude a foraminous carrier. Further more, as stated above, the intended use of the composition was analyzed for patentable weight. It is deemed that they 'breath life' into the claims in that the prior art product must not be precluded to use for those purpose. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

Applicant argues that "The polymer matrix of the medical skin patch of the present invention comprises at least one essential oil (e.g., an inhalable decongestant, as recited in the present claims), at least one hydrophile polymer (e.g., gums) and at least one pressure-sensitive adhesive polymer. In addition, the polymer matrix of the medical skin patch of the present invention further comprises at least one substance having an absorbent effect and/or at least one substance having an emulsifying effect. With respect to the hydrophile polymer and the pressure-sensitive polymer, both being present in the polymer matrix, it is respectfully submitted that Block, et al. teach that the ointment either contains a hydrophilic vehicle or a pressure-sensitive adhesive (i.e., the hydrophobic vehicle). Block, et al. fail to explicitly teach or disclose that the ointment may comprise both a hydrophilic and a hydrophobic vehicle. It is further respectfully submitted that it should be realized that the water content of the matrix of the medicinal skin patch pursuant to the present invention is less than 5% by weight despite the presence of the hydrophile polymer(s). To the contrary, Block, et al. teach that the hydrophilic ointment contains water (col. 3, line 15), whereas the medicinal skin patch of the present invention enables absorption of a large amount of moisture with losing its structural integrity in the absence of any carrier" (page 16, 1st -3rd paragraphs).

This is not found persuasive. First of all, the current applicant does not claim having "both a hydrophilic and a hydrophobic vehicle". Even if it does, since Block et al teach using hydrophilic or hydrophobic material (although Block et al do not explicitly teach using both a hydrophilic and a hydrophobic vehicle simultaneously), one of the ordinary skills in the art would use both hydrophilic and hydrophobic with reasonable expectation of success due to

Block et al's teachings. Secondly, although Block, et al. teach that the hydrophilic ointment may contain water, Block, et al. also teach that "it is preferred that the entire patch be non-occlusive, i.e., capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch" (col 2, lines 50-55). Therefore, since the patch allows moisture from skin to escape, it certain will also allow the water in the ointment to escape till a minimum amount of water is remaining. In addition, ointment, as its name suggests, is viscous semisolid preparation, one of the ordinary skills in the art would recognize the fact that only minimum amount of water that is allowed in the preparation.

With regard to Kelley, Applicant argues that "the reference pertains to transdermal therapeutic patches for percutaneous administration of anti-aging compounds. Thus, the reference pertains to a substantially different medicinal field than the invention discussed in Block, et al. (more specifically, the reference concerns a cosmetic application) and concerns very different purposes. In contrast to a transdermal administration of an active ingredient, the medicinal skin patches of the present invention and Block, et al. concern evaporation of volatile decongestants from the patch, and the subsequent inhalation of the evaporated volatile decongestants from the patch. Inhalation and transdermal administration are different routes of drug delivery which rely on very different mechanical properties, and therefore cannot be compared with each other. Therefore, it is submitted that one skilled in the art who is concerned with realizing administration forms for inhalation therapy in the form of a patch would not have referred to prior art such as Kelley, which discloses transdermal delivery" (page 17, 1st paragraph). Applicant further argues that "In addition, it is submitted that Kelley teaches that an emulsifying agent enhances topical absorption of certain

drugs. However, since the Block, et al. reference does not pertain to transdermal drug delivery, one skilled in the art cannot infer any necessity (i.e. there would be no motivation) as to why the emulsifying agent of Kelley should be incorporated into an inhalation therapy patch in accordance with Block, et al (page 17, last paragraph). Applicant further argues that "it would not be obvious for one skilled in the art to incorporate an emulsifying agent into a hydrophile pressure-sensitive adhesive polymer matrix comprising at least one essential oil, at least one hydrophile polymer and at least one pressure-sensitive adhesive polymer for improving stability and manufacturability of a patch for inhalation therapy. Still further, even if one skilled in the art were to combine said teachings, each and every limitation of the present claims would not be disclosed (page 18, 1st paragraph).

This is not found persuasive. Both Block et al and Kelley teach a patch, which are drawn to the same subject matter as currently being claimed. Secondly, one of the ordinary skills in the art would have the motivation of incorporating the emulsifying agent of Kelley into the patch of Block, et al since Block et al teach "vaporaization of the inhalable decongestant is facilitated by providing the potential for greatly increasing its exposed surface area" (see Abstract), thus by incorporating emulsifying agent into the composition, the inhalable decongestant, which are essential oils, could increase its surface exposing potential, more readily spread on the surface of the patch, which would facilitate the vaporaization of the material. In addition, Block et al also suggest using adhesive such as acrylate emulsion adhesive (col 8, lines 15-20), and a resin emulsion adhesive (claim 11), which is deemed to contain emulsifying agent by itself.

Applicant further argues that "Additionally, even if one skilled in the art were to consider Block, et al. alone, or in combination with the cited secondary references, each and

every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered (page 14, 2nd paragraph) (page 14, 2nd paragraph from the bottom).

Regarding to the limitation to the amount of other components, such as essential oil, emulsifying substance, moisturizers, hydrophile polymer, and pressure-sensitive adhesive polymer, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For instance, the amount of essential oil should be varied according to the congestion condition of the patient that is needed, and consequently the amount of emulsifying substance should also change in order to form a stable emulsion. Meanwhile the adjustment of the amount of the polymer will play an important part in changing the adhesiveness of the patch, and the viscosity of the emulsion so as to find a balance between “attach" and “detach”.

As indicated above, the combination of Block et al and secondary references make the current invention obvious, and from the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Patricia Leith/

Primary Examiner, Art Unit 1655